United States District Court, C.D. California, Western Division.

EDWARDS LIFESCIENCES CORP. and Edwards Lifesciences LLC,

Plaintiffs. v. ST. JUDE MEDICAL, INC. and St. Jude Medical Products, Inc, Defendants.

No. CV 00-07091 CAS (AJWx)

Aug. 29, 2003.

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ORDER CONSTRUING CLAIMS

CHRISTINA A. SNYDER, District Judge.

Plaintiffs Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively "Edwards") are the holders of United States Patents No. 6,283,993 (the "'993 patent") relating to the repair or replacement of human heart valves. FN1 On June 29, 2000, Edwards filed a complaint alleging that products manufactured by defendants St. Jude Medical, Inc. and St. Jude Medical Products, Inc. (collectively "St. Jude") infringe the Edwards patent. The parties disagree as to the meaning of certain claim terms in the Edwards patent, and seek to have the Court construe those terms. The Court held a hearing on claim construction on May 9, 2003, and took the matter under submission.

I. Subject Matter of the Patents

The Edwards patent concerns medical devices used in connection with the repair and replacement of diseased human heart valves, in particular the mitral valve. The mitral valve is situated in the opening between two of the heart's four chambers, the left atrium and the left ventricle. A healthy mitral valve allows blood to flow in one direction between these two chambers, while preventing it from flowing in the other direction. In one phase of the heart's operation, oxygenated blood flows from the lungs into the left atrium and then passes through the mitral valve into the left ventricle. In a second phase, the left ventricle contracts in order to pump the oxygenated blood through the aorta into the body's arterial system. During this phase, a healthy mitral valve closes under pressure to prevent blood from being pumped backward into the left atrium.

In general terms, the mitral valve has two components. The perimeter of the valve, which consists of a ring of tissue which is oval or somewhat D-shaped, is known as the valve "annulus." One side of the valve annulus, referred to as the "anterior" portion, is more rigid and slightly straighter than the more curved and

flexible "posterior" portion. Two flaps of tissue, called valve "leaflets," are attached to the annulus and provide the sealing function of the valve. The anterior leaflet, which is connected to the anterior portion of the valve annulus, is larger than the posterior leaflet, which is connected to the posterior portion of the valve annulus. The anterior leaflet is structured in such a way as to "swing" about the rigid tissue forming the anterior portion of the valve annulus. When blood is pumped from the left atrium into the left ventricle, the mitral anterior leaflet swings open into the ventricle to permit blood to flow into the ventricle. By contrast, when the left ventricle pumps blood into the aorta, the blood pressure in the ventricle swings the mitral valve's anterior leaflet shut against the posterior leaflet and prevents blood from flowing back into the left atrium.

Heart disease can affect both the valve annulus and the valve leaflets. In some forms of heart disease, the valve annulus loses its shape and stretches, or becomes dilated. As the diameter of the annulus grows, the leaflets that are attached to the annulus pull back from each other, leaving a gap which compromises the sealing function of the valve. One surgical procedure for correcting this problem, known as "annuloplasty," reshapes the valve annulus by sewing a prostheses, known as an "annuloplasty ring" and similar in shape to all or part of a healthy annulus, onto the diseased annulus in such a way that the diseased annulus is reshaped into its original form. The '993 patent discloses a rigid holder assembly designed to hold an annuloplasty ring in place while it is being surgically implanted.

II. Legal Standard

A. Patent Infringement

Patent infringement requires that an accused product have all the same elements present in the claim of the patent, or substantial equivalents thereof. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40, 117 S.Ct. 1040, 137 L.Ed.2d 146 (1997). If even one element, or limitation, is not present, the accused product does not literally infringe as a matter of law. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1581 (Fed.Cir.1996). If an accused product does not literally infringe, it may still infringe a claim under the doctrine of equivalents if an element of the product is the substantial equivalent of the otherwise missing claim limitation. Sage Products, Inc. v. Devon Indus., Inc., 126 F.3d 1420, 1423 (Fed.Cir.1997) (holding that a claim element from the corresponding aspects of the accused device"). The doctrine of equivalents is limited by the countervailing doctrine of prosecution history estoppel, which precludes a patent holder from reviving subject matter that was surrendered in the proceedings before the Patent Examiner, even if equivalent to the subject matter expressly claimed. Warner-Jenkinson, 520 U.S. at 30. The patent holder bears the burden of showing that an amendment to the patent does not surrender a particular equivalent. Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki, 535 U.S. 722, 122 S.Ct. 1831, 1842, 152 L.Ed.2d 944 (2002).

A two-step analysis is performed to evaluate patent infringement. CAE Screenplates, Inc. v. Heinrich Fiedler GmbH & Co., KG, 224 F.3d 1308 (Fed.Cir.2000). "First, the claims must be correctly construed to determine the scope of the claims. Second, the claims must be compared to the accused device" to determine if the limitations are met. Kahn v. Gen. Motors, Corp., 135 F.3d 1472, 1476 (Fed.Cir.1998). While claim construction is solely a matter of law for the court, Markman v. Westview Instruments, Inc., 52 F.3d 967, 979-80 (Fed.Cir.1995), *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996), a determination of infringement, both literal and under the doctrine of equivalents, is a question of fact. Insituform Technologies v. Cat Contracting, Inc., 161 F.3d 688, 692 (Fed.Cir.1998).

B. Claim Construction

Claim interpretation begins with an examination of the intrinsic evidence of record, which includes the patent claims, FN2 the specification, FN3 and, if in evidence, the prosecution history FN4 and prior art.FN5 Vitronics, 90 F.3d at 1582, 1584. Courts also may use extrinsic evidence, for example expert or inventor

testimony, to resolve ambiguities in the disputed claim terms, but only if the intrinsic evidence does not resolve the ambiguities. Id. at 1583-84. Further, although technically extrinsic evidence, dictionaries, encyclopedias, and technical treatises may be consulted at any time to help determine the meaning of claim terms. Id. at 1584 n. 6; Texas Digital Systems, Inc. v. Telegenix, Inc., 308 F.3d 1193, 1203 (Fed.Cir.2002); Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1378 (Fed.Cir.2002).FN6 All such evidence-both intrinsic and extrinsic-should be viewed from the perspective of a person of ordinary skill in the relevant art. Markman, 52 F.3d at 979-80.FN7

Generally, courts begin with a "heavy presumption" that "the terms in the claim are to be given their ordinary and accustomed meaning." Johnson Worldwide Association, Inc. v. Zebco Corp., 175 F.3d 985, 989 (Fed.Cir.1999): see also Gart v. Logitech, Inc. ., 254 F.3d 1334, 1341 (Fed.Cir.2001). "An accused infringer may overcome this 'heavy presumption' and narrow a claim term's ordinary meaning, but he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history." CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002) (quoting Johnson Worldwide, 175 F.3d at 989). Rather, "a court may constrict the meaning of a claim term in at least one of four ways." Id. First, the claim term will not be given its ordinary meaning "if the patentee has chosen to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term." Johnson Worldwide, 175 F.3d at 990; see also Texas Digital Systems, 308 F.3d at 1204 ("Indeed, the intrinsic record may show that the specification uses the words in a manner clearly inconsistent with the ordinary meaning reflected, for example, in a dictionary definition. In such a case, the inconsistent dictionary definition must be rejected."). Second, a claim term will not have its ordinary meaning "if the intrinsic evidence shows that the patentee distinguished that term from prior art on the basis of a particular embodiment, expressly disclaimed subject matter, FN8 or described a particular embodiment as important to the invention." CCS Fitness, 288 F.3d at 1366-67. See, e.g., Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378 (Fed.Cir.1998); SciMed Life Sys., Inc. v. Adv. Cardiovascular Sys., Inc., 242 F.3d 1337, 1343-44 (Fed.Cir.2001); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1301 (Fed.Cir.1999). Third, a claim term will not receive its ordinary meaning "if the term 'chosen by the patentee so deprive[s] the claim of clarity' as to require resort to the other intrinsic evidence for a definite meaning." CCS Fitness, 288 F.3d at 1367 (quoting Johnson Worldwide, 175 F.3d at 990). Fourth, if a claim is phrased in step- or mean-plusfunction format, a claim term does not cover more than the corresponding structure or step disclosed in the specification, and the equivalents thereto. 35 U.S. C. s. 112 para. 6; CCS Fitness, 28 F.3d at 1367.

Thus, although courts may look to intrinsic and extrinsic evidence, courts "perform this consultation" to determine whether any of the reasons for abandoning the ordinary meaning are applicable. Gart, 254 F.3d at 1341. In the absence of one or more of the circumstances set forth above, courts must follow the general rule that claim terms are to be given their ordinary meaning. *Id.; Inverness*, 309 F.3d at 1370-73 (holding that nothing in the patent's claim language, specification, or prosecution history contradicted or altered the plain meaning of the unambiguous claim term "mobility" and thus it was error for the district court to construe the claim term at issue not in accordance with its plain meaning).

III. Discussion

A. The '993 Patent Claim Language

The '993 Patent, entitled "Annuloplasty Ring Delivery System" discloses a rigid holder assembly for use with a flexible annuloplasty ring. The rigid holder temporarily provides rigidity and fixed dimension to the flexible annuloplasty ring and acts as a guide that allows the surgeon to control the ring's reshaping of the valve annulus during implantation. The '993 patent has three independent claims, which read as follows:

Claim 1

A holder in combination with an annuloplasty ring, comprising:

an annuloplasty ring;

a rigid body defining at least a partial circumferential edge about which the annuloplasty ring may be fitted, the body having a visibility window defined within the circumferential edge;

a plurality of cutting guides formed in the body adjacent the circumferential edge; and

a plurality of sutures tautly attaching the annuloplasty ring about the circumferential edge, both ends of each suture being secured to the rigid body with a middle portion threaded through the annuloplasty ring.

Claim 20

A substantially rigid holder in combination with an annuloplasty ring, comprising:

a flexible annuloplasty ring;

a body having an outer edge for holding the flexible annuloplasty ring in a plane around the outer edge;

at least one thread releasably retaining the annuloplasty ring around the outer edge in a taut fashion;

a thread guide on the body spaced from the plane of the annuloplasty ring and including a surface supporting the thread, the thread guide having a cutting guide groove opening at the surface for insertion of a cutting tool therein to cut the thread and thereby release the annuloplasty ring from the holder.

Claim 45

A holder in combination with an annuloplasty ring, comprising:

an annuloplasty ring;

a body having an outer circumferential edge shaped to match the shape of a healthy anatomical heart valve annulus;

a plurality of apertures in the body spaced around the circumferential edge;

a plurality of cutting guides spaced around the circumferential edge; and

a plurality of sutures securing the annuloplasty ring to the circumferential edge of the body, each suture being secured at both ends to the body and being threaded there between through a first aperture, through the annuloplasty ring, through a second aperture, across one of the cutting guides, through a third aperture, again through the annuloplasty ring, and through a fourth aperture.

'993 Patent, cols. 13-16.

The parties dispute the meaning of the following claim terms: (1) "edge" (Claims 1, 20, 45); (2) "annuloplasty ring" (Claims 1, 20, 45); (3) "visibility window" (Claim 1); (4) "plurality of sutures tautly attaching the annuloplasty ring about the circumferential edge" (Claim 1); "at least one thread releasably retaining the annuloplasty ring around the outer edge in a taut fashion" (Claim 20); "plurality of sutures securing the annuloplasty ring to the circumferential edge of the body" (Claim 45); and (5) "thread guide on the body spaced from the plane of the annuloplasty ring" (Claim 20).

B. Claim Construction

1. "Edge"

As set forth fully above, the three claim limitations at issue read as follows:

Claim 1: "a rigid body defining at least a partial circumferential edge about which the annuloplasty ring may be fitted, the body having a visibility window defined within the circumferential edge"

Claim 20: "a body having an outer edge for holding the flexible annuloplasty ring in a plane around the outer edge"

Claim 45: "a body having an outer circumferential edge shaped to match the shape of a healthy anatomical heart valve annulus"

Plaintiffs argue that "edge," as used in the '993 Patent, must be construed in accordance with what plaintiffs argue is its relevant ordinary meaning: "a narrow surface or side of a thin object as distinguished from its broad surfaces." Plaintiffs argue that none of the common meanings of "edge" as understood in its this sense limit the term "edge" to any particular cross-sectional shape, nor do these definitions require that the edge be such that it restrains an object against up an down movement, and thus defendants' construction improperly imposes such limitations into its construction of the claim term. Pl. Op. Br. at 15-16. Defendants counter that the ordinary definition of edge, if one exists, is inapplicable here. Defendants contend that in light of plaintiffs' implicit definition of the term "edge," the prosecution history, the vagueness of the term to one skilled in the relevant art, and the means-plus-function expression of the claim limitations using "edge," the Court should construe "edge" as "a channel or trough ... having two sides, which may be of varying length, and which restrain the movement of an annuloplasty ring against both up and down movement."

a. Ordinary Usage

As set forth above, the Court begins with the "heavy presumption" that a claim term should be construed according to its ordinary and accustomed meaning. Johnson Worldwide, 175 F.3d at 989. In determining the ordinary and customary meaning of claim terms, "[d]ictionaries ... are particularly useful" and thus often serve as a starting point in this inquiry. Texas Digital Systems, 308 F.3d at 1203; Inverness, 309 F.3d at 1372. Next, it is important to compare the general dictionary meanings of a claim term with the use of the claim term in the context of the patent. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1300 (Fed.Cir.2003). The intrinsic record should be consulted to ensure that the meaning (or meanings) chosen is the one "most consistent with the use of the words by the inventor." *Id.* However, "[c]onsulting the written description and prosecution history as a threshold step in the claim construction process, before any effort is made to discern the ordinary and customary meanings attributed to the words themselves, invites a violation of our precedent counseling against importing limitions into the claims." Texas Digital, 308 F.3d at 1204.

"Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor." Id. at 1203. And, "[i]f more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." *Id.; Inverness*, 309 F.3d at 1378-79.

A review of several dictionaries' definitions of the term "edge" indicates that the word "edge," like many words, has different meanings depending upon the context in which it is used. Importantly, several definitions support plaintiffs' proposed construction of the "edge" in its ordinary usage in the context of the

'993 patent.FN9 The Oxford English Dictionary defines "edge" as "[o]f a thin flat object: [o]ne of the narrow surfaces showing the 'thickness' or smallest dimension, as distinguished from the broad surfaces." Oxford English Dictionary ("OED") (1989).FN10 Webster's Third New International Dictionary (defines "edge" as "the relatively thin surface or side of any object bounded by plane surfaces <the [edge] of a book>." Webster's Third New Int'l Dictionary ("Webster's Third") (1993).FN11 Further, Merriam Webster's Collegiate Dictionary defines "edge" as "the narrow part adjacent to a border <the [edge] of a deck>." Merriam Webster's Collegiate Dictionary ("Webster's Collegiate") (10th ed.1996). These definitions demonstrate that the in its ordinary and accustomed usage, the term "edge" may be used to identify the narrow peripheral side or surface of an object, as distinguished from its broader surfaces.FN12

Further supporting that this is the ordinary usage of the term "edge" in the context of the '993 patent, plaintiff has submitted prior art in the field of heart valve replacement surgery. *See supra* n. 5 (discussing examination of prior art in determining definition of term as understood by persons skilled in the relevant art). For example, U.S. Patent No. 4,759,758, entitled "Prosthetic Heart Valve," states: "The cutaway section is defined by downwardly curving edges 4 ending in horizontal edge 5 coplanar with base 2. A rounded corner is formed where curved edges 4 join the edges of upper portion 3, to avoid the possibility of tearing tissue." PI.Ex. F at 2:56-60 (referring to Fig. 1). Figure 1 shows that the various "edges" described are narrow, flat surfaces which form the margin at the intersection of broader surfaces. Id . & Fig. 1. In addition, U.S. Patent No. 4,950,287, entitled "Bicurved Leaflet(s) Prosthetic Heart Valve," states "[t]he leaflets 10, 12 have trailing edges 10 *b* and 12 *b* that are also bevelled...." PI.Ex. O & Fig. 3. Figure 3 shows the that "trailing edges" of the leaflets are narrow, flat surfaces along the outer periphery from the broader bevelled surfaces. Thus, plaintiffs have shown that prior art in the field uses the claim term "edge" in a manner consistent with the ordinary definition discussed above.

Further, examination of the specification and the prosecution history, as discussed below, does not indicate that the definition of edge set forth above is otherwise limited as defendants suggest.

b. Defendants' Arguments for Deviating from Ordinary Usage

i. Patentee as Lexicographer

Defendants contend that the patentees' use of the claim term "edge" throughout the '993 Patent has implicitly limited "edge" to include a "groove-like" channel or trough, particularly because each of the eleven figures depicting embodiments of the invention depicts an edge containing such a groove. Def. Op. Br. at 26; Def. Resp. Br. at 4-5.FN13

However, the case cited by defendants, Bell Atlantic Network Services. Inc. v. Covad Communications Group, 262 F.3d 1258 (Fed.Cir.2001), does not support defendants' position. Rather, in *Bell Atlantic*, the court explicitly recognized that "[i]n redefining the meaning of particular claim terms away from the ordinary meaning, the intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice that the patentee intended to so redefine the claim term.... The specification must exhibit an 'express intent to impart a novel meaning' to claim terms.' " *Id*. at 1268 (citations omitted). *See also* CCS Fitness, 288 F.3d at 1366 (holding that a defendant cannot overcome the presumption that the ordinary meaning applies "simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history ... [because] our case law makes it clear that a patentee need not 'describe in the specification every conceivable and possible future embodiment of his invention.' ") (quoting Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed.Cir.2001)). Thus, although a patentee's redefinition of a claim term may be implicit. Bell Atlantic, 262 F.3d at 1268, there must be clear language in the specification, for example, in the written description of the preferred embodiment, evidencing the intention to redefine the term. *Id*.

Defendants have not argued that any part of the written description evidences an intention to implicitly

redefine the term "edge," but defendants merely argue that the figures accompanying the written descriptions demonstrate that all of the illustrations of "edges" appear to contain a groove. Def. Op. Br. at 26; Def. Resp. Br. at 4-5. Under the authorities cited above, it is clear that it is insufficient for defendants merely to point to the figures included in the patent to demonstrate that the patentee implicitly redefined a claim term in a manner inconsistent with the term's ordinary meaning.

Moreover, plaintiffs have cited portions of the written description which indicate that the outwardly facing edge can either be flat or have a depression. For example, the summary of the invention states "the holder assembly includes a body having an outwardly facing surface, generally flat, against which the suture guide is tautly positioned Preferably, this surface is formed with at least one depression for receiving a portion of the suture guide." '993 Patent, 4:59-64.

Further, the Court notes that the term "edge" is not defined in the specification. And, although the description of the preferred embodiment mentions with reference to several of the embodiments that the suture guide is fitted into a "groove" or "trough," *see* '993 Patent, 7:13-20 (referring to figures 2-5), there is no "clear statement[] of scope" limiting the invention to such embodiment. *See* Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1328 (Fed.Cir.2002). It is improper to import limitations from the preferred embodiment into the claims if such limitations are not present in the claims themselves. Id. at 1327-28 ("The term 'clip' is not defined in the specification or in the prosecution history, and although the specification describes only one embodiment of the clip, no 'clear statements of scope' limit the term 'clip' to having a 'single pair of legs.'... Absent such clear statements of scope, we are constrained to follow the language of the claims, rather than that of the written description."). Thus, the Court turns to the language of the claims.

Neither party disputes that the plain language of the independent claims does not require "edge" to have channel or trough. Further, the dependent claims read as follows:

15. The combination of claim 1, wherein the circumferential edge is a groove.

16. The combination of claim 1, wherein the circumferential edge is a trough.

17. The combination of claim 1, wherein the circumferential edge is a depression.

18. The combination of claim 1, wherein the circumferential edge is a channel.

19. The combination of claim 1, wherein the circumferential edge is generally flat.

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40. The combination of claim 20, wherein the outer edge is a groove.

- 41. The combination of claim 20, wherein the outer edge is a trough.
- 42. The combination of claim 20, wherein the outer edge is a depression.
- 43. The combination of claim 20, wherein the outer edge is a channel.
- 44. The combination of claim 20, wherein the outer edge is generally flat.

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^{51.} The combination of claim 45, wherein the circumferential edge is a groove.

- 52. The combination of claim 45, wherein the circumferential edge is a trough.
- 53. The combination of claim 45, wherein the circumferential edge is a depression.
- 54. The combination of claim 45, wherein the circumferential edge is a channel.
- 55. The combination of claim 45, wherein the circumferential edge is generally flat.

'993 Patent, cols. 13-16.

Plaintiffs argue that under the doctrine of claim differentiation, if the edges are "generally flat" for dependent claims numbered 19, 44, and 55, "then the edges of the broader independent claims cannot be construed to exclude 'generally flat.' To construe 'edge' to mean U-shaped or J-shaped grooves with two sides in the independent claims, as St. Jude proposes, would render these dependent claims meaningless, i.e., an edge cannot be both U-shaped and generally flat." Pl. Op. Br. at 19. Additionally, plaintiffs argue that whereas several of the dependent claims require the "edge" to have a "trough" or "channel" respectively (e.g. dependent claims 16, 41, 52, 18, 43, and 54), "[t]o adopt St. Jude's propose[d] construction, which expressly limits the edge of the independent claims to a trough or channel, would render all six of these dependent claims superfluous," and thus such a construction must be rejected under the doctrine of claim differentiation. Id.

The Federal Circuit has held that " '[t]here is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between the claims is significant.' " Comark Communications, Inc. v. Harris Corp., 156 F.3d 1182, 1187 (Fed.Cir.1998) (quoting Tandon Corp. v. United States Int'l Trade Comm'n, 831 F.2d 1017, 1023 (Fed.Cir.1987)); *see, e.g.*, Beachcombers v. Wildewood Creative Prod., Inc., 31 F.3d 1154, 1162 (Fed.Cir.1994) ("[T]his claim interpretation suffers from an infirmity-it would result in claim 9 having the same scope as claim 1, and thus would render claim 9 superfluous. Accordingly, it is presumptively unreasonable.").

The Court agrees with plaintiffs' position that to adopt defendants' construction limiting "edge" in independent claims 1, 20, and 45 to an edge having a "channel" or "trough" contradicts the "generally flat" language in dependent claims 19, 44, and 55, and also renders dependent claims 16, 41, 52, 18, 43, and 54 superfluous. The presumption therefore arises that such a construction is unreasonable and defendants bear the burden of rebutting that presumption. To do so, defendants contend that the "generally flat" language appearing in dependent claims 19, 44, and 55 was used by the '993 patentees to distinguish the present invention "from other types of ring and holder assemblies in which the edge takes on, for example, a 'saddle-shape' (i.e., the ring and holder assembly curve upward or downward at an angle away from the general plane of the rest of the ring.)." Def. Op. Br. at 20; see also id. at 21 (figure depicting "saddleshaped" holder assembly). However, defendants have not cited to any portion of the prosecution history showing that plaintiffs inserted the "generally flat" language in order to overcome any prior art; nor does there appear to have been any statement by plaintiffs to this effect. Rather, defendants have cited only to the testimony of one of the alleged inventors to support their position. Id. at 21 (citing declaration of Than Nguyen).FN14 However, it is only proper for a court to consider extrinsic evidence, including inventor testimony, where "in the rare circumstance that the court is unable to determine the meaning of the asserted claims after assessing the intrinsic evidence." Bell Atlantic, 262 F.3d at 1268-69; see also discussion infra n. 22.FN15 Because defendants have cited to no other evidence supporting their construction of the independent and dependent claims that is consistent with the doctrine of claim differentiation, the Court rejects defendants' argument as to the "generally flat" language. Further, the Court concludes that defendants have failed to show that the patentees explicitly or implicitly adopted a meaning of "edge" other than the ordinary meaning set forth above.

ii. Vagueness of Term

Defendants next contend that the term "edge" (or "circumferential edge" or "outer edge") is so vague that one skilled in the art can only reconcile the claim language with the inventor's disclosure without resort to other evidence. Def. Op. Br. at 26. To support their argument, defendants have cited to the testimony another of the named inventors, Delos Cosgrove, who testified at his deposition with respect to the '420 Patent that the term "groove" lacks an accepted meaning in the medical profession. *See id.* (citing Ex. L at 105:9-24). Based thereon, defendants argue that "[t]he term 'edge' connotes even less structure than 'groove.' If 'groove' has no generally accepted structural meaning in the art, then logically neither would the less specific term 'edge.' " *Id.* First, as the Court previously noted, it is improper to rely on inventor testimony here; moreover, the inventor testimony submitted by defendants is in relation to an entirely different claim term, which term is used in the context of a different patent (the '420 Patent), and thus this testimony is entitled to no weight with respect to the determination of the definition of the term "edge" as used in the '993 Patent. In any event, as set forth above, plaintiffs have sufficiently shown that the term "edge" not only has an ordinary meaning which, in light of the intrinsic record, is properly applied in the context of the '993 Patent, but plaintiffs have also shown that their proffered definition is consistent with the use of the term "edge" by others skilled in the relevant art.

Defendants further argue that "Edwards' citations to various definitions of the term 'edge' demonstrate just how amorphous the term 'edge' really is, and that it certainly does not connote sufficient structure by itself." Def. Op. Br. at 27. However, defendants' argument is not supported by the case law. For example, in *Texas Digital*, the Federal Circuit recently reiterated the principle that "[i]f more than one dictionary definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all such consistent meanings." Texas Digital, 308 F.3d at 1203; *see, also e.g.*, Rexnord, 274 F.3d at 1343 (holding that the claim term "portion" may be interpreted in accordance with the dictionary definitions to encompass both "separate" and "integral" parts of an object). Thus, the mere existence of multiple dictionary definitions does not render a claim term impermissibly vague.

iii. Prosecution History

"The prosecution history limits the interpretations of the claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall*, 54 F.3d at 1574.

At issue in the present litigation are a family of related patents originating from Patent Application 387,909 (the '909 application), filed in 1989 which was abandoned.FN16 *See* Pl.Ex. D; Def. Ex. G. The '420 Patent, which issued in 1993, was a second continuation application from the '909 application. *See id*. By contrast, the '993 Patent flowed from a separate strand of the '909 application, and it followed from two continuation-in-part applications, four continuation applications, and a divisional application. *See* id.

"When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the *same* claim limitation." Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed.Cir.1999) (emphasis added); Jonsson v. Stanley Works, 903 F.2d 812, 819 (Fed.Cir.1990) (holding that statements made in prosecution history of patents issued from same parent application are "relevant to an understanding" the use of the same claim term in the related patents). However, "arguments made in [the prosecution of] a related application do not automatically apply to *different* claims in a separate application." Biogen, Inc. v. Berlex Labs., 318 F.3d 1132, 1139 (Fed.Cir.2003) (emphasis added).

Defendants argue that "each of the patents in the chain contained claims that required a groove-like structure," and in particular, that during prosecution of the '420 Patent, the patentees' use of the claim language "groove means" limited the circumferential surface on the assembly holder to one that contains a

trough or channel. Def. Op. Br. at 29. Defendants urge the Court to construe "edge" and "groove means" as the same claim term, but they obviously are not, and defendants have pointed to nothing in the record supporting their assertion that plaintiffs have used the terms to mean the same thing.FN17 Rather, the '993 Patent and the '420 Patent derived from separate strains of the '909 application, and have a different degree of relatedness to the parent application where the '420 Patent was merely a continuation of a continuation, but the '993 Patent followed from applications including continuations-in-part, continuations, and a division. *See* discussion *supra* n. 16 and accompanying text. Thus, the Court concludes that the prosecution history as to the claim term "groove means" in the '420 Patent does not limit the construction of the claim term "edge" in the '993 Patent.FN18 Because defendants have failed to identify, nor has the Court located, any part of the '993 Patent's prosecution history in which plaintiffs disclaimed the construction of "edge" which plaintiffs have proposed here, the Court finds that defendants have failed to show that the ordinary meaning of "edge" does not apply.FN19

iv. Means-Plus-Function

Defendants next contend that the limitations "circumferential edge" (Claims 1 and 45) and "outer edge" (Claim 20) are means-plus-function limitations, and thus are limited to the corresponding structures (or their equivalents) described in the specification. Def. Op. Br. at 22-26.

Under the Patent Act, "a patentee may define the structure for performing a particular function generically ... provided that it discloses specific structure[s] corresponding to that means in the patent specification." Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1360 (Fed.Cir.2000). Section 112, paragraph 6 of the Patent Act governing such "means-plus-function" limitations provides:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. s. 112, para. 6.

Defendants first argue that each of the limitations containing "edge" is generic. Next, citing the language in Claim 20, defendants argue that "edge" does not describe a structural component, but merely a means for "holding the annuloplasty ring around the holder."

However, as plaintiffs point out, whereas "a claim limitation that actually uses the word 'means' will invoke a rebuttable presumption that s. 112, para. 6 applies ... a claim term that does not use 'means' will trigger the rebuttable presumption that s. 112 para. 6 does not apply." CCS Fitness, 288 F.3d at 1369 (citations omitted).FN20 In this case, the claims at issue do not phrase the "edge" limitation in means-plus-function language, thereby triggering the rebuttable presumption that s. 112 para. 6 does not govern. *See id*. Defendants may rebut this presumption if they show that the claim term fails to "recite sufficiently definite structure" or to recite a "function without reciting sufficient structure for performing that function." Watts v. XL Sys., 232 F.3d 877, 880 (Fed.Cir.2000). In performing this inquiry, the court inquires into whether the term has a "reasonably well understood meaning [] in the art as [a] name[] for structure." *Id.; see also* Greenberg v. Ethicon Endo-Surgery, Inc., 91 F.3d 1580, 1583 (Fed.Cir.1996).

Identifying references to the use of "edge" in prior art, plaintiffs have shown that others of ordinary skill in the art of cardiac valve surgery understand the use of the term "edge" as a structural feature. For example, U.S. Patent No. 4,759,758, cited supra, states: "The cutaway section is defined by downwardly curving edges 4 ending in horizontal edge 5 coplanar with base 2. A rounded corner is formed where curved edges 4 join the edges of upper portion 3, to avoid the possibility of tearing tissue." Pl.Ex. F at 2:56-60 (referring to Figure 1). Additionally, U.S. Patent No. 4,078,268, entitled "Heart Valve Prosthesis," states: "The edges 153

and 154, as shown in FIG. 14, have a semi-circular or rounded configuration." Pl.Ex. G at 9:37-38 (referring to Figure 14). These uses of the term "edge" show an understanding that the claim term denotes a structural claim, and not a functional one.

Further, even though the elements in Claim 20, for example, include a function, namely "holding the flexible annuloplasty ring," the claim itself contains sufficient structural limitations for performing that function, *i.e.*, that the edge is on a "body" and that it holds the ring "in a plane around" that "body." Claims 1 and 45 illustrate the structural terms of the respective claims: "a rigid body defining at least a partial circumferential edge ..., the body having a visibility window defined within the circumferential edge" (Claim 1) and "a body having an outer circumferential edge shaped to match the shape of a healthy anatomical heart valve annulus" (Claim 45). Thus, the "edge" elements in the claims provide sufficient structure to remove them from the realm of s. 112 para. 6. *See*, *e.g.*, *Al- Site*, 174 F.3d at 1318 (reversing district court's conclusion that claim term "eyeglass hanger member" was means-plus-function even where the claims contained functional language because the claims also contained sufficient structural language).FN21

Defendants have failed to rebut the presumption that the claim term "edge," which claim limitation is not described with the word "means," is a means-plus-function limitation, where "edge" is shown to be a structural term as used by one of ordinary skill in the relevant art, and where the other claim terms provide "sufficient structure" for performing the recited function. *See* Watts, 232 F.3d at 881; *Al- Site*, 174 F.3d at 1318.

Because defendants have failed to rebut the presumption that the claim term "edge" as used in the '993 patent should not be interpreted according to its ordinary and customary meaning in the context of the '993 Patent-"a narrow surface or side of a this object as distinguishes from its broad surfaces"-the Court concludes that this is the proper construction of "edge." FN22

2. "Annuloplasty Ring"

The parties dispute two aspects of the term "annuloplasty ring." First, they dispute whether the ring includes flexible, semi-rigid and rigid rings, or instead, whether the '993 Patent includes only rings that are flexible. Second, the parties dispute whether "annuloplasty ring" may encompass a structure that is fully annular, or whether the '993 Patent teaches only a partial ring.FN23

a. Flexibility

Beginning with the language in claims 1, 20, and 45 describing annuloplasty rings, it is apparent that the term "flexible" is used only in claim 20. However, defendants argue that the annuloplasty rings in claims 1 and 45 also are limited to flexible rings. Plaintiffs, by contrast, argue that since claims 1 and 45 do not expressly include a limitation that the annuloplasty ring be "flexible," then all other known types of rings, including rigid and semi-rigid rings, should be included in the construction of those claims.

As set forth above, under the doctrine of claim differentiation the presumption arises that claims 1, 20 and 45 are different in scope. *See* Comark, 156 F.3d at 1187. However, the presumption may be overcome by the disclosure in the written description or by evidence contained in the prosecution history. Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1368 (Fed.Cir.2000).

The patent at issue in *Kraft* contained two different independent claims containing claim language describing the back paneling of a food package. *Id.* at 1365, & 1367 n. 2. Claim 1 contained the claim limitation "a protecting back paneling" and claim 2 contained the claim limitation "a back panel comprising a flat relatively stuff planar sheet." *Id.* Although the district court began with the presumption that the scope of the claims was different, the court concluded that the presumption had been overcome by the written description and the prosecution history. *Id.* at 1368. Thus, the court construed the claim term "protecting

back panel," as "a relatively rigid structure[] that serves the function of protecting the food tray compartments from indentation and damage." *Id.* at 1365 (quoting district court order). In upholding the district court's construction, the Federal Circuit held that the district court had properly concluded that the presumption was overcome where "every disclosed embodiment that employs a back panel employs one that is relatively stiff," and where the "relatively rigid characteristic of the 'protecting back panel' " promoted at least one of its purposes, as stated in the written description. *Id.* at 1368.

Kraft is instructive here. Although the presumption of different claim scope arises in the present case with respect to the "flexible" limitation used only in claim 20 and not claims 1 and 45, "[the doctrine of] claim differentiation can not broaden claims beyond their correct scope." Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1480 (Fed.Cir.1998). Thus, the Court turns to an examination of the written description.

The section entitled "Background of the Invention" sets forth the problems encountered with previous forms of rings used in annuloplasty. For example, rigid and semi-rigid rings, because they flex very little, interfere with normal cardiac movement after implantation, and the result is that they sometimes place sufficient stress on the sutures used to implant the ring so as to tear the sutures loose. *See* '993 Patent, 1:19-32; 2:19-34. Fully flexible rings also present different problems in that they do not provide support to the area of suture during implantation of the prosthesis, thereby causing bunching of the sutures around localized areas (*i.e.*, "multiple plications"), and leads to the distortion of the shape of the valve annulus which interferes with cardiac function. *Id.*, 2:47-65. In light of the problems with prior annuloplasty ring prostheses, the patent describes its goal as follows:

For use in annuloplasty, as in other applications, it is desirable that a suture guide be entirely flexible, light weight, and compliant while having sufficient strength to withstand stress placed upon the sutures sewn through and around it The need exists for a means of temporarily providing rigidity and fixed dimension to the suture guide during the surgery, but rendering the suture guide freely flexible once the surgery has been completed."

Id., 3:35-47; *see also* 4:41-45 ("The present invention overcomes the above discussed advantages by providing an assembly for holding a substantially flexible suture guide in a substantially taut position ...); 5:20-22 ("[T]he holder device is designed to lend a temporary rigidity or tautness to the suture guide while lending to it a shape selected to facilitate the suturing task.").

Further, the description of the preferred embodiment discloses only descriptions of the annuloplasty ring (or suture guide) as a freely flexible member: "The suture guide of the invention is formed from a freely flexible rib encased within a woven cloth covering." '993 Patent, 5:64-66. See also 6:12-15 ("When the suture guide is released from the holder, it will assume any shape that that portion of the body organ or vessel assumes in accordance with the dynamic function of the organ or vessel."); 6:27-28 ("The freely flexible suture guide ..."); 6:38-41 ("Due to its flexibility, the length of the suture guide 10 can be manipulated to assume any desired shape, i.e., circular, C-shaped, straight, curvilinear and straight segments."); 6:52-56 ("The outer covering 16 is formed from any biocompatible material having sufficient strength to serve as an anchor to sutures without tearing and sufficient flexibility to be formed into a light covering for rib 14 without restricting flexibility of suture guide 10."). None of the inventions' preferred embodiments, nor the remainder of the written description, contains any disclosure as to a rigid or semirigid suture guide or annuloplasty ring. Rather, an inflexible annuloplasty ring or suture guide appears inconsistent with, and even unsuitable for use with, the preferred embodiments described in the '993 Patent. Thus, the Court concludes that the presumption that the term "flexible" limits only claim 20 is overcome, and the claim limitation "annuloplasty ring" as used in all three independent claims, 1, 20, and 45, is construed as a freely and entirely flexible member. Such construction also is consistent with the stated purposed of the invention, *i.e.*, to provide temporary rigidity to a flexible annuloplasty ring during the surgical procedure to prevent multiple plications from occurring, but also to permit flexibility after the

surgery is performed so that the sutures do not tear loose. *See* Kraft, 203 F.3d at 1368 (upholding the district court's construction, in part, because the construction was consistent with "at least one purpose of 'protecting back panel' " set forth in the written description).

Next, to support their contention that only the annuloplasty ring in claim 20 should be construed with the limitation "flexible," plaintiffs cite Reinshaw PLC v. Marposs Societa Per Azioni, 158 F.3d 1243 (Fed.Cir.1998), in which the Federal Circuit noted that "if an apparatus claim recites a general structure (e.g., a noun) without limiting that structure to a specific subset of structures (e.g., with an adjective), we will generally construe the claim to cover all known types of that structure that are supported by the patent disclosure." Id. at 1250. Although the "annuloplasty ring" claimed in claims 1 and 45 is not modified with the adjective "flexible," as the Federal Circuit also has noted, the presumption that arises under the doctrine of claim differentiation is "not a hard and fast rule." Comark, 156 F.3d at 1186. As set forth above, by the disclosure in the written description, the patentee limited the "suture guide," including the "annuloplasty ring" claimed in each of the independent claims of the '993 Patent, to one that is "flexible." *See* Kraft, 203 F.3d at 1368 ("That the patentee chose several words in drafting a particular limitation of one claim, but fewer (though similar) words in drafting the corresponding limitation in another, does not mandate different interpretations of the two limitations.").FN24

Finally, the Court notes that with respect to the parent '909 application (abandoned), the applicants submitted a response to the examiner's rejection of certain of the dependent claims 1-3, 6, 8, 9 and 13-20 on the basis of obviousness and anticipation and by U.S. Patent No. 4,865,600 issued to Carpentier et al. *See* Def. Ex. Z (July 31, 1989 letter to PTO in re application of Cosgrove et al., Serial No. 387,909). In their remarks, the applicants contended that the Carpentier invention was not an annuloplasty ring prosthesis, but merely a heart valve assembly. Id. at 2-3. Further, the applicants stated the following with respect to the annuloplasty ring prosthesis claimed in their application:

The applicants further contest any submission that Carpentier, either alone or in combination with Martin et al., renders the claims obvious. The primary distinction between the heart valve holders of Carpentier and applicants' annuloplasty ring prosthesis holder is related to the differences between the devices being held. An annuloplasty ring prosthesis, and specifically the prosthesis recited in the applicants' claims, is flexible. Flexible annuloplasty ring prostheses possess little, if any, structure support, and are defined by generally limp body structures. The heart valve holders of Carpentier et al. (4,865,600), or even for that matter Martin et al. (4,585,453) are rigid structures ...

Id. at 3. Thus, in the prosecution history of parent application '909, the applicants disclaim any annuloplasty ring prosthesis that is not flexible, and use the flexibility as a method of overcoming prior art in the field. *See* Kraft, 203 F.3d at 1368.

b. Partial or Fully Annular Ring

The parties dispute whether the claim term "annuloplasty ring" in the context of the '993 Patent encompasses only partial or open rings, or also includes fully annular rings. Neither party disputes that the ordinary meaning of "annuloplasty ring" as understood by those skilled in the relevant art includes both partial or open (e.g.C-shaped) rings and fully annular (e.g. circular or D-shaped) rings .FN25 And, an examination of prior art in the field of annuloplasty supports this conclusion. For example, several of the patents expressly described in the '993 Patent's written description refer to an "annuloplasty ring" that is fully annular. *See, e.g.*, United States Patents No. 3,656,185, entitled "Cardiac Valvular Support Prosthesis" at 1:30-44 (referring to figure 1, depicting a fully annular D-shaped ring); 4,290,151, entitled "Adjustable Annular Prosthesis for Cardiac Surgery" at 2:21-54 (referring to Figure 2, depicting a fully annular ring); and 4,055,861, entitled "Support for a Natural Human Heart Valve" at 1:20-49 (referring to figure 1, depicting a fully annular Using to Figure 1, depicting a fully annular Using to Figure 1, depicting a fully annular D-shaped ring). FN26

Where the ordinary meaning of the claim limitation "annuloplasty ring" includes both partial or open rings and fully annular rings, that meaning should be applied unless defendants have sufficiently shown a reason to deviate from it. Defendants contend that the Court's prior claim construction order, the '993 Patent's specification, and inventor testimony all support their construction of annuloplasty ring as limited to a partial or open ring. Plaintiffs, by contrast, argue that none of these reasons is sufficient to overcome the ordinary meaning of annuloplasty ring.

First, defendants contend that because the Court, in its prior order construing the '420 Patent, construed the term "annuloplasty ring" to be limited to "a partial or open annuloplasty ring," and because there are no additional disclosures in the '993 Patent's specification requiring a different construction of the term, the same construction should be applied here because the same claim term is at issue. Def. Op. Br. at 10-11. However, as plaintiffs point out, neither of the reasons supporting the Court's construction of the claim limitation "annuloplasty ring" in the '420 Patent are applicable with respect to the use of that claim limitation in the context of the '993 Patent.

In its prior order, the Court construed the term "groove means" as being a U-shaped structure, or as containing a "channel or trough having two sides which restrain the movement of an annuloplasty ring both up and down." *See* June 27, 2002 Order at 18. Based on this construction of "groove means," the Court concluded that only a partial or open ring was disclosed in the '420 Patent because the "groove means" structure, as construed by the Court, "would be unsuitable for use with full annuloplasty rings." Id. at 19. Further supporting its construction of "annuloplasty ring" the Court found that "the specification of the '420 Patent as it relates to the claims at issue discloses only a partial ring." Id. (citing '420 Patent, 4:68-5:2, & Figs. 4 & 5 (depicting a C-shaped ring)). Thus, the Court concluded that "it is apparent that 'annuloplasty ring' should be construed in the '420 Patent to mean 'partial or open annuloplasty ring.' " Id.

However, with respect to the '993 Patent, as set forth above in detail, the Court has not construed the "edge" of the holder assembly as requiring a similar trough or channel. Rather, dependent claims 19, 44, and 55 claim holder assemblies with outer or circumferential edges that are "generally flat" and which do not contain a trough or channel restraining the up and down movement of the annuloplasty ring. Thus, insofar as the Court's reasoning with respect to the construction of "annuloplasty ring" in the '420 Patent depended on the construction of "groove means," the same construction is inapposite here. Further, the specification of the '993 Patent discloses a fully annular annuloplasty ring. For example, Figure 1B depicts a fully annular suture guide, sutured together at its ends to form a complete ring. '993 Patent, Fig. 1 (suture guide labeled number "10" as used in description of preferred embodiments). And, the description of the suture guide in the preferred embodiment provides:

[T]he suture guide 10 is an elongate, flexible member of predetermined dimension. Due to its flexibility, the length of suture guide 10 can be manipulated to assume any desired shape, i.e., circular, C-shaped, straight, curvilinear or a combination of curvilinear and straight segments. In Fig. 1B suture guide 10 is shown as shaped into a ring by suturing the two ends together with sutures 11.

Id., 6:35-44. Defendants argue that figure 1B does not represent an annuloplasty ring, but merely a flexible suture guide that can be formed into a full ring. Def. Resp. Br. at 9-10. Defendants argue that "Figure 1B is clearly never depicted on the annuloplasty ring holder of Figures 1-5." Id. at 9. However, defendants' argument is contradicted by further inspection of the description of the preferred embodiment of the '993 Patent, which provides:

Figs. 2 through 5 illustrate in greater detail the guide mount assembly 18 and how the *suture guide 10 is mounted thereon*. Guide mount assembly 18 includes a guide support 20. For illustrative purposes, the suture guide assembly here shown is one intended for use in plication of a distended heart valve annulus. *Therefore facing edge of guide support 20 is generally C-shaped or annular*, having a shape circumferential dimension to achieve in the human heart annulus by means of annuloplasty surgery. More particularly,

support 20 is generally lenticular, having a C-shaped portion 28, with its ends connected by s straight side.

'993 Patent, 7:1-12 (emphasis added).

Thus, the above-quoted language clearly describes suture guide 10, which is that depicted in Figure 1B, as used in annuloplasty. Further, figures 3 and 5, which defendants admit depict annuloplasty ring holders, show suture guide 10 on the annuloplasty holder. *See* '993 Patent, Figs. 3 & 5. Finally, wherein the above-quote language discloses that the guide support on the holder assembly is "generally C-shaped or *annular*," it is apparent that plaintiffs have not implicitly redefined the use of the term "annuloplasty ring" merely to include partial rings. In light of the discussion above, the Court concludes that the proper construction of annuloplasty ring as used in the '993 Patent includes partial or fully annular annuloplasty rings. FN27

3. "Visibility Window"

The claim limitation "visibility window" appears only in claim 1: "a rigid body defining at least a partial circumferential edge about which the annuloplasty ring maybe fitted, the body having a visibility window defined within the circumferential edge." '993 Patent. The central dispute between the parties is whether the visibility window must be an open portion defined within the holder body, or whether it also may be a covered with a transparent substance. Plaintiffs propose that the term "visibility window" be construed as "a portion of the holder body through which the heart valve may be observed during surgery," while defendants propose that the term be construed as "an opening within the circumferential edge through which the heart valve may be observed during the suturing process."

Plaintiffs contend that the ordinary meaning of the term "window" "is not limited to a physical opening in the holder body, but also includes any portion of the holder that allows the surgeon to visually observe the underlying heart valve." Pl. Op. Br. at 34. Defendants respond, however, that the specification does not disclose any use of transparent material to cover the "window," but rather, that the entire specification supports a construction that the "visibility window" must be an open space formed in the holder body. Def. Op. Br. at 33; Def. Resp. Br. at 14.

Plaintiffs are correct that the term "window" may be defined as an opening sometimes covered by a transparent material, e.g., "an opening in a wall of a building or a side of a vehicle to admit light usu. through a transparent or translucent material (as glass), usu, to permit vision through the wall or side, and often to admit air." Webster's Third.FN28 However, this is not the only definition of "window." For example, as defendants suggest, "window" also may be defined as an open space defined within a larger space, e.g., "an opening in a partition or a wall through which business is carried on (as by a bank teller or a ticket agent)." Id. Moreover, an additional definition demonstrates that the term window may encompass an opening that is either open or covered with transparent material: "any of various openings resembling or suggestive of a window as: (1) a small opening through which it is possible to see: SLOT, ... (3) a transparent panel (as in an envelope, paper bag or carton)". Id. Because a term may be construed to encompass more than one dictionary definition "consistent with use of the words in the intrinsic evidence," Texas Digital, 308 F.3d at 1204, FN29 the Court next turns to the context in which the term "window" is used to aid in determining its meaning as used by the inventor. See Brookhill-Wilk 1, 334 F.3d at 1300 (holding that to determine the inventor's use of a disputed claim term, dictionary definitions should be compared with the context in which the claim term is used). The structure claimed, is a "visibility window defined within the circumferential edge." '993 Patent. Nothing in the language of the claim limitation indicates that the window defined within the edge is or is not covered by any transparent material. As such, it appears that both definitions of "window," *i.e.*, that it is a covered space or an open space are plausible readings of the claim language.

That the term "visibility window" as used in independent claim 1 is broad enough to encompass both definitions is further supported by the doctrine of claim differentiation. Dependents claim 8 reads:

Claim 8: The combination of claim 1, wherein the rigid body comprises a planar member extending generally in a plane within the circumferential edge, and wherein the visibility window comprises an opening formed in the planar member.

'993 Patent. To limit "visibility window" as used in claim 1 to an "opening within the circumferential edge" as defendants propose, would render dependent claim 8 superfluous. Thus, the presumption arises that the scope of claims 1 and 8 are different. *See* Comark, 156 F.3d at 1187.

Defendants contend that the presumption arising under the doctrine of claim differentiation is rebutted where the written specification lacks any discussion of the use of a transparent material in combination with the visibility window and where none of the figures depicting the assembly device show any such transparent material used. Def. Op. Br. at 33.

The specification is void of any definition of the term "visibility window," and the only reference to the subject of visibility is in the description of figures 2-5: "The arrangement of mount assembly 18 including, in this instance, a curved guide support 20 with hub 22 and spokes 24, allows the surgeon to visually observe the heart valve during the suturing process." '993 Patent, 7:25-29. Contrary to what defendants suggest, however, the mere absence of discussion or depiction of any transparent material covering a visibility window is not sufficient to demonstrate the patentees' intent to limit the scope of the term "visibility window" to an open section. *See* CCS Fitness, 288 F.3d at 1366-67 (patentee must "expressly disclaim[] subject matter"); Texas Digital Systems, 308 F.3d at 1204 (disclaimer of scope occurs where inventor uses "us[es] words or expressions of manifest exclusion or restriction); Inverness, 309 F.3d at 1372 (requiring a "clear and unambiguous disclaimer of scope").FN30

Because defendants have pointed to nothing in the written description or prosecution history that overcomes the presumption that claims 1 and 8 are different in scope, and because the ordinary definition of "window" and the context in which it is used in the '993 Patent encompasses both an open space and a space covered with a transparent material, the Court concludes that the proper construction of the term "visibility window" is "a section defined within the holder body through which the heart valve may be observed during the suturing process."

4. Attachment of Ring to Holder

As set forth fully above, the three claim limitations at issue read as follows:

Claim 1: "plurality of sutures tautly attaching the annuloplasty ring about the circumferential edge"

Claim 20: "at least one thread releasably retaining the annuloplasty ring around the outer edge in a taut fashion"

Claim 45: "plurality of sutures securing the annuloplasty ring to the circumferential edge of the body"

'993 Patent.FN31 The central dispute with respect to how the ring is attached to the holder body is whether the ring is attached by sutures that apply a vertical force, radial force, or a combination thereof. Defendants contend that "the plurality of sutures" (claims 1 and 45) or the "thread" (claim 20) attaching the ring to the holder body must apply at least some force in the same plane as the edge of the holder body, *i.e.*, a radial or horizontal plane. Def. Op. Br. at 30-32; Def. Resp. Br. at 13-14. Defendants argue that merely because some radial force must be applied does not exclude the possibility that vertical force also is applied to attach the ring to the holder body. Def. Op. Br. at 31. Plaintiffs argue, however, that the claims are not so limited because they permit the ring to be attached to the holder body with radial force only, with vertical force only, or with a combination of radial and vertical force. Pl. Op. Br. at 28.

Examination of the claim language itself demonstrates that the claims are broad enough to encompass sutures or threads attaching the ring to the holder body by vertical force only, radial force only, or a combination of both. For example, the disputed claim language from claim 1, when read with the remainder of its claim language, reads:

a plurality of sutures tautly attaching the annuloplasty ring about the circumferential edge, *both ends of each suture being secured to the rigid body with a middle portion threaded through the* annuloplasty ring.

'993 Patent, Claim 1 (emphasis added). Thus, the plain language of the claim discloses that part of the attaching suture(s) is passed through the ring itself and the ends of the suture are secured to the holder body. Nothing in this language prohibits the sutures from being passed vertically through the ring and secured to the holder. Although claims 20 and 45, are silent on this issue, nothing in the express language of claims 20 and 45 precludes attachment of the ring to the holder by threads or sutures applying force in a vertical plane. Further, the claim terms "about" (claim 1), "around" (claim 20) and "to" (claim 45) merely describe the relative location of the ring with respect to the edge, and do not require that the attaching sutures or thread apply force in a radial plane. Nor do the terms "tautly attach" (claim 1), "retain in a taut fashion" (claim 20), or "securing" (claim 45) require that vertical force be applied; these terms merely indicate that the ring is to be fashioned to the holder body without any slack. *See* Webster's Collegiate (defining "taut" as: "having no give or slack; ... not loose or flabby"); id. (defining "secure" as "[to] hold fast").

The written description sets forth several preferred embodiments regarding the attachment of the ring to the holder body. One preferred embodiment teaches that the suture guide is passed through an aperture close to the end of the holder body, the suture is then passed through the body of the suture guide, and the ends of the ring are secured by sutures passed through apertures close to the end portions of the holder body. *See* '993 Patent, 8:17-34 FN32 & Figs. 5. Two additional preferred embodiments teach that the sutures used to attach the ring to the holder body are tied passed through the opposing ends of the suture guide, threaded across the open portion of a C-shaped holder, and then are tied off through apertures located at opposing ends of the holder body. *See* '993 Patent, 35-56 & Figs. 5, 6.FN33 There is no dispute that in all three of these preferred embodiments, force is applied in the plane horizontal to the holder's edge. Another preferred embodiment teaches that the ring is secured by sutures passed through the ring and through apertures in the holder body located at various points along the holder's edge. *See* '993 Patent, 11:3-5 & Fig. 13.FN34 Force is thus again applied in the plane horizontal to the holder's edge. It also appears, however, from the depiction of this preferred embodiment in figure 13 that vertical force also is applied, where the sutures are fed through cutting guides raised above the holder body. Thus, radial and vertical force appear to be applied in attaching the ring to the holder body in this preferred embodiment. *Id*.

Defendants point to the embodiments and figures discussed above to support their contention that the invention requires at least some radial force be applied in attaching the ring to the holder body. However, defendants have not identified any portion of the written description evidencing a "clear statement[] of scope" by which the patentees limited the means of tautly attaching the ring to the holder body to those forms expressed in the preferred embodiments. Teleflex, 299 F.3d at 1328. As set forth above, it is improper to import limitations from the preferred embodiments or figures into the construction of claims terms that are broader in the absence of such "clear statement[] of scope" by the patentee. *Id.* Thus, the Court will not limit its construction of the claims on this basis.

Defendants also rely the July 31, 1989 letter submitted to the PTO with respect to the '909 application, in which the applicants discussed the differences between their proposed invention and prior art. *See* Def. Ex. Z. However, although the applicants discussed in their remarks the means for attaching the ring to the holder body, the applicants did not disclaim a means of attaching the ring to the holder body with vertical force only.FN35 *Id.* at 3; *cf.* Def. Ex. S (U.S. Patent No. 4,865,600 issued to Carptentier et al.).

Where the claim language supports attachment of the ring to the holder body by either vertical or horizontal force, the Court will not import limitations from the preferred embodiments into the claims, nor will the Court import alleged disclaimers from prosecution history which do not clearly disclaim particular interpretation of the claims. *See* Vitronics, 90 F.3d at 1583; *Southwall*, 54 F.3d 1576 ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution."). Thus, the Court construes the sutures or thread attaching the ring to the holder body as permitting attachment by vertical force only, radial force only, or a combination of force in both planes.

5. "thread guide on the body spaced from the plane of the annuloplasty ring"

Claim 20 recites a limitation that the holder assembly contain "a thread guide on the body spaced from the plane of the annuloplasty ring...." Defendants contend that the thread guide must be located on top of the holder body, while plaintiffs contend that the thread guide also may be recessed into the body of the holder assembly.

To support their construction of the claim limitation, plaintiffs argue that the claim term "on" may be defined to include "in," and thus "a thread guide *on* the body" may be construed as "a thread guide *in* the body". Webster's Third (defining "on" as "used as a function word to indicate presence within <rode there [on] a train>") FN36; Webster's New World Dictionary, 3rd ed. (defining "on" as "in the surface of [a scar on the body]") FN37.

Defendants, by contrast, argue that the term "on" in the context of the '993 Patent is "[u]sed to indicate position above and supported by or in contact with." Def. Op. Br. at 33 (quoting definition of "on" from American Heritage College Dictionary 3rd ed.1993); FN38 *see also* Webster's Third (defining on as "used as a function word to indicate position over and in contact with that which supports from beneath <the book is [on] the table>"); Webster's New World Dictionary (defining "on" as "in a position above, but in contact with an support by; upon"). Thus, defendants argue that the limitation reciting the thread guide must be construed as "a platform over and in contact with the body and raised above the plane of the annuloplasty ring to guide threads."

While, as plaintiffs have shown the ordinary definition of "on" may include "in," the context of the claim language here excludes such definition of "on." Claim 20 recites "a thread guide on the body *spaced from the plane of the* annuloplasty ring and including a surface supporting the thread, the thread guide having a cutting guide groove opening at the surface for insertion of a cutting tool...." '993 Patent, col. 14. Thus, the plain language requires the thread guide to be in a different plane than the annuloplasty ring. Because the annuloplasty ring, which is fitted "about," "around" or "to" the edge of the holder body, resides in the same plane as the holder, the thread guide, which must be "spaced from" that plane, must be in a different plane than the holder, *i.e.*, above and in contact with it. Thus, the Court construes the thread guide which is "on the body" as being above and in contact with the holder body.

While not dispositive, the specification supports this construction. For example, figures 11, 12, and 13 depict holder bodies containing thread guides raised above the body, which thread guides each contain a "surface supporting the thread" and "having a cutting guide groove opening at the surface for insertion of a cutting tool" as required by the plain language of claim 20. Further, the description of the only preferred embodiment of an annuloplasty ring holder which describes the thread guide reads:

Referring to figure 13, cutting guides 208, 214 and 220 consist of a *raised platform* with a shallow groove 228 formed therein through which the suture passes and a deeper groove 230 formed in the platform perpendicular to the shallow groove through which a cutting tool may pass in order to cut the suture at the location lying over the deeper groove.

'993 Patent, 11:31-38 (emphasis added).FN39 Nothing in the specification or the prosecution history

indicates that a construction other than the one set forth is appropriate.

IT IS SO ORDERED.

FN1. Plaintiffs also hold United States Patents No. 5,061,277 (the "277 patent"), No. 5,350,420 (the "420 patent"), No. 4,372,743 (the "743 patent"), which are related to the same subject matter. On June 27, 2002, the Court issued an order construing the claims that were the subject of those three patents.

FN2. The first source courts turn to in order to define the scope of the invention is "the words of the claims themselves, both asserted and nonasserted." Vitronics, 90 F.3d at 1582. Claim language cannot be interpreted differently in different claims because claim terms must be interpreted consistently. Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed.Cir.1995).

FN3. The specification "contains a written description of the invention that must enable one of ordinary skill in the art to make and use the invention. For claim construction purposes, the description may act as a sort of dictionary, which explains the invention and may define terms used in the claims...." Markman, 52 F.3d at 979. The specification is examined to determine whether the inventor has used a term in a manner inconsistent with its ordinary meaning, and as an aid to understanding the meaning of ambiguous claim language. See Vitronics, 90 F.3d at 1582 ("[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term."); Renishaw PLC v. Marposs Societa Per Azioni, 158 F.3d 1243, 1250 (Fed.Cir.1998) ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."). However, "[a]lthough claims must be read in light of the specification of which they are a part, ... it is improper to read limitations from the written description into a claim" Tate Access Floors, Inc. v. Maxcess Technologies, Inc. 222 F.3d 958, 966 (Fed.Cir.2000); see also Kraft Foods, Inc. v. International Trading Co., 203 F.3d 1362, 1366 (Fed.Cir.2000) ("Although the written description may aid in the proper construction of a claim term, limitations, examples, or embodiments appearing only there may not be read into the claim.").

FN4. The prosecution history "contains the complete record of all the proceedings before the Patent and Trademark Office, including any express representations made by the applicant regarding the scope of the claims [and] is often of critical significance in determining the meaning of the claims." Vitronics, 90 F.3d at 1583. In particular, the prosecution history "limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." Southwall, 54 F.3d at 1576.

FN5. In construing asserted claims, courts may consider "prior art proffered by one of the parties, whether or not cited in the specification or the file history, ... to demonstrate how a disputed term is used by those skilled in the art." Vitronics, 90 F.3d at 1584; *see also* In re Cortright, 165 F.3d 1353, 1358 ("Prior art references may be 'indicative of what all those skills in the art generally believe a certain claim term means.' ") (quoting Vitronics, 90 F.3d at 1584).

FN6. "As resources and references to inform and aid courts and judges in the understanding of technology and terminology, it is entirely proper for both trial and appellate judges to consult these materials at any stage of a litigation, regardless of whether they have been offered by a party in evidence or not." Texas Digital Systems, 308 F.3d at 1203.

FN7. "By examining relevant dictionaries, encyclopedias and treatises to ascertain possible meanings that would have been attributed to the words of the claims by those skilled in the art, and by further utilizing the intrinsic record to select from those possible meanings the one or ones most consistent with the use of the words by the inventor, the full breadth of the limitations intended by the inventor will be more accurately determined and the improper importation of unintended limitations from the written description into the claims will be more easily avoided." Texas Digital Systems, 308 F.3d at 1205.

FN8. Such disavowal occurs only where an inventor "us[es] words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." Texas Digital Systems, 308 F.3d at 1204; *see also* Inverness, 309 F.3d at 1372 (requiring a "clear and unambiguous disclaimer of scope").

FN9. *See*, *e.g.*, Moba B.V. v. Diamond Automation, Inc., 325 F.3d 1306, 1315 (Fed.Cir.2003) (relying on Oxford English Dictionary); *Inverness*, 309 F.3d at 1378 (citing with approval the use of The Shorter Oxford English Dictionary, Webster's Third International Dictionary, and Merriam Webster's Collegiate Dictionary).

FN10. Pl.Ex. M at 364.

FN11. Pl.Ex. L at 722.

FN12. Examination of the claim term "edge" as used in the context of the '993 Patent also indicates that the other definitions of "edge" (*e.g.* "the cutting side of a blade"; "vigor or energy"; "a noticeably harsh or sharp quality"), *see* Webster's Collegiate, are not encompassed in the usage of "edge" in the claims and context of the '993 Patent. *See* Brookhill-Wilk 1, 334 F.3d at 1300; *Inverness*, 309 F.3d at 1378 ("It is simple to rule out may of the definitions of 'on' as contextually irrelevant.").

FN13. Defendants do not contend, and the record does not support a finding, that the '993 Patent explicitly defines the term "edge" in a manner inconsistent with the definition proffered by defendants.

FN14. Plaintiffs have objected to Nguyen's declaration on several grounds, including bias, but in light of the Court's conclusion that this extrinsic evidence is not properly considered here, the Court need not rule on these objections.

FN15. Defendants also argue that the "generally flat" language in the written description is used to describe the plane in which the edge exists in relation to the holder, distinguishing the device from a saddle-shaped holder which has an edge that is not in the same plane as the holder and thus is not "generally flat." Def. Op. Br. at 20-21; Def. Resp. Brief at 8. However, defendants' interpretation is not supported by the text, which reads: "the holder assembly includes a body having an outwardly facing surface, generally flat, against which the suture guide is tautly positioned.... Preferably, this surface is formed with at least one depression for receiving a portion of the suture guide." '993 Patent, 4:59-64. In this part of the written description, the phrase "generally flat" modifies the preceding phrase "outwardly facing surface," indicating that that surface is generally flat. The following sentence is not inconsistent, where is expresses that the surface preferably

contain at least one depression; such is not exclusive language, but an inclusive expression of preference.

FN16. The following terms are used to describe the various types and degrees of relationship that exist among related patents originating with a single patent application:

Parent application: "The original application in a sequence or chain of applications is.. the 'parent.' In case of a chain of three applications, the original may be called the 'grandparent.' "

Continuation application: "A continuation application is a second application which contains the same disclosure as the original application. It may not contain anything that would have been considered 'new matter' if inserted in the original application ."

Continuation-in-part application: "A continuation-in-part application is a second application 'repeating some substantial portion of the earlier application and adding matter not disclosed in the 'earlier application.' Such an application may be used to add improvements developed since the filing date of the parent application or for other purposes."

Divisional application: "A division or a divisional application is 'a later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application. Such a division will normally be used when the [PTO] requires restriction of an application to one of the two or more disclosed independent inventions."

Donald S. Chisum, Chisum on Patents, s.s. 13:03[1]-[4] (Matthew Bender 2002) (citations omitted). FN17. Defendants cite to Exhibit C attached to the declaration of Lisa Partain, and contend that the evidence is the "993 Inventors' Record and Assignment Form." This evidence, however, was not submitted in connection with the '993 Patent. Rather, the document is the "Inventors' Record and Assignment Form" submitted to the PTO in connection with U.S. Patent Application No. 833,600, which was abandoned, but a continuation application of which became the '420 Patent. Thus, it is not, as defendants claim, part of the prosecution history of the '993 Patent.

FN18. Defendants also urge the Court to make the same findings in construing "edge" as the Court made in its prior Order construing "groove means," but for the reasons set forth above, the Court's prior order is not binding on the construction of the claim terms in the '993 Patent.

FN19. Defendants also argue that because the patent examiner rejected the '993 patent for "obviousness-type" double-patenting over the '402 and '336 patents, which patents both contain the term "groove," then because plaintiffs filed a terminal disclaimer in response to the rejection, plaintiffs limited the term "edge" in the '993 Patent to one containing a "groove." Def. Op. Br. at 29. However, as plaintiffs have pointed out, an obviousness-type double-patenting rejection is issued when the PTO considers pending claims obvious in view of another patent by the same inventor; such rejection does not mean that the respective claims are considered the same (which requires a different rejection under 35 U.S.C. s. 101). The terminal disclaimer filed by plaintiffs was merely used as a procedural device to overcome the rejection. *See* Quad Environmental Tech. Corp. v. Union Sanitary District, 946 F.2d 870, 873 (Fed.Cir.1991) ("Voluntary

limitation of the term of the later-issued patent is a convenient response to an obvious-type double patenting rejection, when the statutory requirement of common ownership is met. Any possible enlargement of the term of exclusivity is eliminated, while enabling some limited protection to a patentee's later developments."). The terminal disclaimer, like the rejection itself, does not provide any evidence of similarity or sameness between different claims terms in the respective patents. Id. at 873-74 (explaining "obviousness-type" double-patenting, and holding that a terminal disclaimer, being of "circumscribed availability and effect," does not create an admission or acquiescence in the merits of the rejection); *see also id*. Further, even if the '993 Patent's claims were obvious in view of the one claim in the '402 Patent containing the term "groove," a narrow species may render a broad genus obvious, and thus "edge" as used in the '993 Patent may still be broader than "groove" as used in the '402 Patent. *See, e.g.*, In re Berg, 140 F.3d 1428, 1431-32, 1436-37 (Fed.Cir.1998).

FN20. *See also Al*- Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1318-19 (Fed.Cir.1999) ("[W]hen an element of a claim does not use the term 'means,' treatment as a means-plus-function claim element is generally not appropriate.").

FN21. In reaching its conclusion, the court in *Al-Site* explained the structural terms of the claims as follows: [C]laim 1 of the '*345* patent describes the eyeglass hanger member as "made from flat sheet material" with an "opening means formed ... below [its] upper edge." This structure removes this claim from the purview of s. 112, P 6. Similarly, according to claim 1 of the '*726* patent, the eyeglass hanger member has "an attaching portion attachable to a portion of said frame of said pair of eyeglasses to enable the temples of the frame [to be opened and closed]." This structure also precludes treatment as a means-plus-function claim element.

Al- Site, 174 F.3d at 1318.

FN22. The parties cite to the testimony of the inventors and experts to support their respective proposed constructions of the term "edge" as used in the '993 Patent. However, the Court concludes that such evidence is not properly considered where the meaning of the claim term "edge" is discernible without resort to it. Bell Atlantic, 262 F.3d at 1268-69 ("[I]f the meaning of the claim limitation is apparent from the intrinsic evidence alone, it is improper to rely on extrinsic evidence other than that used to ascertain the ordinary meaning of the claim limitation.... [I]n the rare circumstance that the court is unable to determine the meaning of the asserted claims after assessing the intrinsic evidence, it may look to additional evidence ... [including] expert testimony, articles, and inventor testimony."); *see also* Vitronics, 90 F.3d at 1583-84.

FN23. Plaintiffs' proposed construction of annuloplasty ring is: "An annular or partially annular prosthesis that fits about all or a portion of a heart valve annulus." Defendants' proposed construction is: "[A] partial or open ring that is freely and entirely flexible."

FN24. At oral argument, plaintiffs argued that the purpose of the invention was twofold: first, to give rigidity to the annuloplasty ring during an implantation procedure, and second, to allow the surgeon to position the ring, even a rigid or semi-rigid ring. However, the written description, including the preferred embodiments set forth at length above, does not disclose the use of a rigid or semi-rigid ring.

FN25. *See* Pl. Op. Br. at 20 ("There is no dispute that the ordinary meaning of this term includes both fully annular ('O' or 'D') rings, as well as partially annular ('C') rings."); Def. Resp. Br. at 10 ("St. Jude agrees that the term 'annuoplasty ring,' in general, can mean an open (C-shaped) or a full (complete) ring.".

FN26. These patents are described in the '993 Patent at 2:30-33, 2:35-37; and 3:18-19, respectively. In addition, the patents are attached as exhibits V, W, and X, to the Declaration of Steven R. Daniels in Support of Edwards Lifesciences' Brief in Support of it Claim Construction of the '993 Patent ("Daniels Decl.").

FN27. Defendants also argue that the testimony of Cosgrove and Ngyuen supports their constructions of "annuloplasty ring" as being a flexible, partial ring. However, because the terms may be construed in light of the intrinsic evidence, and no ambiguities remain, resort to such extrinsic evidence is improper. Bell Atlantic, 262 F.3d at 1268-69; Vitronics, 90 F.3d at 1583-84.

FN28. Pl.Ex. L at 355.

FN29. See also Inverness, 309 F.3d at 1378-79.

FN30. Unlike the Court's construction of "annuloplasty ring" where the written description included discussion only of a flexible ring and thereby evidenced the inventor's intent to so limit the scope of "annuloplasty ring," here, there is almost no discussion of the "visibility window." In these circumstances, the Court is unwilling to import the limitation asserted by defendants into the language of the claim.

FN31. The court notes that "plurality" is a common patent term of art meaning two or more. York Prods. v. Central Tractor Farm & Family Ctr., 99 F.3d 1568, 1575 (Fed.Cir.1996). Thus, "plurality of sutures" is construed to mean two or more sutures.

FN32. The written description provides:

One embodiment of the means for releasably attaching suture guide 10 to guide support 20 of guide mount assembly 18 as seen in Fig. 5.... One end 71 of a cord or suture thread 70 is passed through one of the apertures, as illustrated hole 66, and tied off on guide support 20. The other end 73 of suture 70 is passed through the body of suture guide 10 from one end to the other. This end 73 is then passed first through hole 68 and then through and tied off at hole 66.

'993 Patent, 8:17-34

FN33. The stated difference in these preferred embodiments is that in one embodiment, the C-shaped holder includes a guide support joining the ends of the holder body, and in the other embodiment, there is no such guide support. *See* '993 Patent, 35-56; *e.g.*, Figs. 5 & 6.

FN34. The written description of this preferred embodiment reads:

Referring to Fig. 13, suture guide 152 is releasably attached to guide mount 150 by sutures or threads 198, 200, and 202. Suture 198 is tied off at aperture 204 and then passes through one end of the suture guide and up through aperture 206 over cutting guide 208 down through aperture 206 again, through suture guide 152, through aperture 209, then up through aperture 210 where the other end of suture 198 is tied off.

'993 Patent, 11:3-9.

FN35. The July 31, 1989 letter states:

Carpentier does not teach within its four corners the precise arrangements of the releasable retaining means recited in claims 6-10, 14, 15, 16 and 18. Nowhere does Carpentier teach the passing of one or more threads through a portion of the annuloplasty ring, with the ends of the thread being tied to the holder body. First, Carpentier does not teach annuloplasty rings but a hear valve assembly. However, more importantly, the sutures described in Carpentier are not used to tautly retain the hear valve suture ring about the holder body as is specifically required by the applicants' invention.

Def. Ex. Z at 3. FN36. Pl.Ex. L at 351.

FN37. Pl.Ex. AA at 547.

FN38. Def. Ex. S.

FN39. The only figure and description that plaintiffs point to in support of their argument that the thread guide may be recessed into the holder body is figure 15, which is plainly not a representation of an annuloplasty ring holder. *See* '993 Patent, 12:15-8 ("The linear suture guide shown in FIGS. 14 and 15 would be used for any surgical procedure in which the incision is a substantially straight line.").

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